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Notice of Reasons for Rejection
(Translation)

Patent Application No:	2001-363505
Drafting Date:	May 17, 2004
Patent Examiner:	Noriko Mukasa 9735 4B00
Agent:	Hatsushi Shimizu (and one other)
Sections Applied:	Sections 29 (2) and 36

The above-identified application should be rejected for the reasons stated below. If Applicant has any argument against the reasons, such argument should be submitted within three months from the dispatch date of this notice.

Reasons

I. The invention of this application described in the claims indicated below is not patentable under Japanese Patent Law Section 29(2), on the grounds that the invention could have easily been made by a person with ordinary skill in the art to which the invention pertains, prior to the filing of this application, on the basis of the invention described in the documents listed below, which were distributed in Japan or elsewhere prior to the filing of this application, or of the invention publicly available through electric telecommunication lines prior to the filing of this application.

II. The detailed description of the invention of this application fails to comply with the provision of Japanese Patent Law Section 36(4), with respect to the points mentioned below.

III. The claims of this application fail to comply with the requirements under Japanese Patent Law Section 36(6)(ii), with respect to the points mentioned below.

Note (for the cited documents, see List of Cited Documents)

Reason I

・ Claim(s): 1-18

・Cited Document(s): 1-3

・Remarks:

Cited Document 1 discloses that HIV-I replication was inhibited by transducing cells with both sense and antisense HIV-1 RNAs.

Cited Document 2 discloses alteration of gene expression by introducing sense and antisense RNA fragments of a target gene into plant cells, and that the RNA fragments are comprised in two different RNA molecules.

Cited Document 3 discloses a recombinant alphavirus particle which carries a vector construct capable of directing the expression of a palliative in cells infected with the alphavirus particle, and that when the palliative is capable of selectively inhibiting expression of a pathogenic gene, the palliative may comprises an antisense RNA complementary to RNA sequences necessary for pathogenicity (claims 48 and 50 of Cited Document 3).

Since Cited Documents 1 and 2 disclose inhibition of target gene expression by introducing sense and antisense RNA for the target gene, it would be obvious to one skilled in the art, upon inhibition of the target gene expression, to introduce RNA into virus particles to transfect cells with them as described in Cited Document 3, which also discloses inhibition of target gene expression.

It would be well within the skill of the art to appropriately use, if necessary, the viral particles thus prepared as a pharmaceutical composition for treatment or prevention of diseases.

Thus, claims 1-18 are obvious over Cited Documents 1-3.

Reason II

(1) Claim 1 recites "a process to inhibit the expression of a target gene in cells or tissue", in which the expression of the target gene is inhibited by infection with viral particles containing single-stranded ribonucleic acid (ssRNA) expressing a sense or antisense RNA strand comprising a sequence homologous to a portion of the target gene. However, considering that in general, translation-inhibitory activity of an antisense oligonucleotide is greatly affected by a subtle change in its sequence or length, one skilled in the art would not be able to select a nucleotide sequence homologous to a portion of a target gene and that inhibits the expression of the target gene without excessive trial and error and complicated and sophisticated experimentation.

All other claims depending from claim 1 and claim X are rejected for the same reason.

As described above, the specification fails to disclose the invention claimed in

claims 1-9 in such a clear and complete manner that one skilled in the art would practice the invention.

(2) Claim 8 recites a process in which "inhibition of said target gene expression demonstrates a phenotypic loss-of-function". However, it is generally unknown whether a phenotypic loss-of-function is actually achieved by introducing antisense and sense RNA to inhibit the gene expression until transduction of RNA is actually conducted. Thus, one skilled in the art would not be able to select the portion responsible for the loss-of-function, without excessive trial and error and complicated and sophisticated experimentation, and the specification fails to disclose the invention in such a clear and complete manner that one skilled in the art would be able to achieve the phenotypic loss of function by using antisense and sense RNA strands comprising nucleotide sequences homologous to a portion of the target gene.

Accordingly, the specification of the present application fails to disclose the invention claimed in claim 8 in such a clear and complete manner that one skilled in the art would easily practice the invention.

(3) Claim 10 recites "use of (a) viral particles containing single stranded ribonucleic acid (ssRNA) and (b) viral particles containing single stranded ribonucleic acid (ssRNA) expressing anti-sense RNA strand (the sense and antisense RNA strands comprise homologous nucleotide sequences of a portion of a target gene) for the preparation of a medicament for treating diseases". In this regard, the specification discloses in Examples that such viral particles were used to inhibit expression of a certain protein, but inhibition of protein expression does not imply the applicability to treatment of diseases (the inhibition might be abolished by a feedback mechanism or by action of another protein that compensates the function of the inhibited protein). Thus, it is unknown whether such viral particles can be used for treatment of diseases.

Claims 11-18 are rejected for the same reason.

Accordingly, the specification of the present application fails to disclose the invention claimed in claims 10-18 in such a clear and complete manner that one skilled in the art would easily practice the invention.

Reason III

Concerning the "homologous nucleotide sequences to a portion of said target gene" recited in claim 1, the specification does not distinctly define what is meant by the term "homologous" found in the claim language, and the invention for which a patent is

sought is indefinite.

Claims 9 and 10 and all other claims depending from these claims are rejected for the same reason.

The term "specific for said target gene" used in claim 7 is also indefinite.

Accordingly, claims 1-18 are rejected as being indefinite.

If any reasons for rejection are newly found, such reasons will be notified.

List of Cited Documents

1. Nucleic Acids Research, July, 1998, Vol. 26, No. 13, pp. 3270-3278
2. WO 99/61631
3. Japanese Translation of International Patent Application, JP-A H09-503657

Record of the Result of Prior Art Search

· Technical field searched:	Int. Cl. (7):	C12N15/00-15/90
	DBs:	BIOSIS/WPI (DIALOG)

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